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August 31, 1999

Office of Compliance (CHFZ-307)
Attn: Electronic Products Branch (Mr. Dennis)
Center for Devices of Radiological Health
2098 Gaither Road
Rockville, MD 20850

Dear Mr. Dennis,

I am responding to Mr. Iten's report (accession number 9411585-02) filed on March 15, 1999, requesting FDA approval of the AN/PAQ-4C, Infrared Aiming Light. The AN/PAQ-4C is a Class IIIb Infrared Laser Aiming Device. Therefore, in accordance with 21 CFR 1010.4, Insight Technology, Inc. formally requests a variance based on the following information.

The AN/PAQ-4C aiming light projects an infrared laser beam, which cannot be seen with the naked eye but can be seen with night vision devices. The device incorporates a normally OFF/mornentarily ON pressure switch that would serve the function of both the emission indicator and beam attenuator within the intent of the regulations. This allows the operator to conduct surveillance operations without detection, under the cloak of darkness. Any audible or visible emission indicator could senously compromise the safety of law enforcement officers in performance of their duties.

The AN/PAQ-4C mounts on various weapons with mounting brackets and adapters. Pressing on the ON/OFF, switch lever activates the AN/PAQ-4C. The switch connects power from two AA Batteries to an internal electronic circuit, which produces the infrared laser beam. The AN/PAQ-4C will only project publication while the operator is pressing the ON/OFF switch. A protective grad that its closer around the ON/OFF switch lever prevents inadvertent activation of the AN/PAQ-4C Internal lenses focus the infrared light into a narrow beam.

Adjusters are used to zero the Aiming Light to the weapon. The direction is adjusted by rotating the mechanical adjusters with click detents once

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the weapon, the Aiming Light projects the beam along the line of fire of the weapon. The Optical Baffle prevents off-axis viewing of the Aiming Light beam. The Beam Divergence of the AN/PAQ-4C is 0.3 mr.

The proper handling of a firearm as directed by Military and Law Enforcement Community requires the muzzle of the weapon to remain pointed at the ground until a threat requires defensive action. This action permits an additional safety precaution against accidental exposure to the IR Laser should the operator inadvertently press the OFF/ON switch and activate the laser.

The intended use of this product is by government, military and law enforcement agencies in the routine execution of their duties. Insight Technology, Inc. restricts the sale of the AN/PAQ-4C, Laser Aiming light to government, military and law enforcement agencies, including law enforcement personnel. Insight Technology, Inc. restricts the resale of the AN/PAQ-4C Laser Aiming light to government, military and law enforcement agencies. A statement of this policy is provided on the request for quote (figure 1) and technical data sheet (figure 2). Please note that the technical data sheet is a preliminary draft. The final draft will include the correct Class IIIb label.

I have included a sample design of the Danger Label (figure 3) for the AN/ PAQ-4C. This label will be affixed to the AN/PAQ-4C in place of the Caution Label used on the standard military Aiming Light. We have opted not to include the model number and production date as part of the label. Each AN/PAQ-4C possesses a recorded serial number, which provides a catalogued production date and all corresponding test data on file with Insight Technology, Inc. A label containing the necessary contact information of Insight Technology, Inc. (figure 4) will be located on the side of the battery compartment.

If you have any questions or need additional data please call me at (603) 626-4800 EXT: 2451 or fax me on (603) 647-7234. As I mentioned in an e-mail to you during the week of August 22nd, Mr. Iten has resigned his position with Insight Technology. Please note the appropriate changes to 1.1 and the necessary corrections to 6.2 of the Laser Product Report. In addition, I have included a current copy of the Certificate of Calibration for the AN/PAQ-4C test equipment.

Sincerely,

Chris Feinauer

Manager Business Development